

UNITED STATES DISTRICT
FOR THE
WESTERN DISTRICT OF MISSOURI

ALAINA FERRARA,
8521 N. Eastern Ave.
Kansas City, Missouri 64157,

Plaintiff,

v.

BAYER CORPORATION,
an Indiana corporation
c/o CSC – Lawyers Incorporating Service Company)
221 Bolivar
Jefferson City, MO 65101,

BAYER HEALTHCARE
PHARMACEUTICALS INC.,
a Delaware corporation
c/o CSC – Lawyers Incorporating Service Company)
221 Bolivar
Jefferson City, MO 65101

BAYER HEALTHCARE, LLC,
a Delaware corporation
c/o CSC – Lawyers Incorporating Service Company)
221 Bolivar
Jefferson City, MO 65101

Defendants.

Civil Action No. _____

COMPLAINT AND
JURY DEMAND

COMPLAINT

Plaintiff Alaina Ferrara, by and through her counsel of record, and for her Complaint against Defendants, alleges as follows:

PARTIES AND JURISDICTION

1. This is an action brought by Plaintiff Alaina Ferrara, who used the combination oral contraceptive Yasmin, also known generically as drospirenone and ethinyl estradiol (hereinafter collectively referred to as “Yaz/Yasmin”).

2. Plaintiff Alaina Ferrara was prescribed, purchased and ingested Yaz/Yasmin. While using Yaz/Yasmin, she suffered from Gallbladder Disease beginning about May, 2009 and lasting through June, 2009. Ultimately, Plaintiff underwent gallbladder removal surgery on or about June 16, 2009.

3. Plaintiff Alaina Ferrara is a resident and citizen of Missouri.

4. Plaintiff Alaina Ferrara alleges an amount in controversy in excess of Seventy-Five Thousand Dollars (\$75,000.00), exclusive of interest and costs.

5. Defendant Bayer Corporation is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Defendant Bayer Corporation is the sole member of Bayer Healthcare LLC, which owns 100% of Schering Berlin, Inc., which owns 100% of Defendant Bayer HealthCare Pharmaceuticals, Inc. As such, Defendant Bayer Corporation is a parent of Defendant Bayer Healthcare Pharmaceuticals, Inc.

6. At relevant times, Defendant Bayer Corporation was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz/Yasmin. At relevant times, Defendant Bayer Corporation conducted regular and sustained business in Missouri by selling and distributing its products in Missouri and engaged in substantial commerce and business activity in Jackson County.

7. Defendant Bayer Healthcare Pharmaceuticals, Inc., formerly known as Bayer Pharmaceuticals Corporation, and also formerly known Berlex Laboratories, Inc., which was formerly known as Berlex, Inc., is a Delaware corporation, with its principal place of business at 6 West Belt Road, Wayne, New Jersey, 07470. Bayer Healthcare Pharmaceuticals, Inc. was

created by the integration of Bayer Healthcare and Berlex Laboratories. Defendant Bayer Healthcare Pharmaceuticals, Inc. is the U.S.-based pharmaceuticals unit of Schering Berlin, Inc. and is a division of Bayer AG.

8. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a corporate successor to Berlex Laboratories, Inc. (Berlex), which was formerly known as Berlex, Inc., and as such is obligated for its predecessor's liabilities. Berlex was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling directly and indirectly through third parties or related entities, the drug Yaz/Yasmin.

9. Defendant Bayer Healthcare Pharmaceuticals, Inc. is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz/Yasmin. At relevant times, Defendant Bayer Healthcare Pharmaceuticals, Inc. conducted regular and sustained business in Missouri by selling and distributing its products in Missouri and engaged in substantial commerce and business activity in Jackson County.

10. Defendant Bayer Healthcare, LLC is a Delaware limited liability company, with its principal place of business at 555 White Plains Road, Tarrytown, New York, 10591. Bayer Healthcare, LLC was involved in the integration of Bayer Healthcare and Berlex Laboratories. Defendant Bayer Healthcare, LLC is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz/Yasmin. At relevant times, Defendant

Bayer Healthcare, LLC conducted regular and sustained business in Missouri by selling and distributing its products in Missouri and engaged in substantial commerce and business activity in Jackson County.

11. Defendants Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., and Bayer Healthcare, LLC, are collectively referred to herein as "Bayer" or "Bayer Defendants."

Jurisdiction and Venue

12. This Court has jurisdiction over this action by virtue of 28 U.S.C. §1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars (\$75,000.00) exclusive of interest and costs and because there is a complete diversity of citizenship between plaintiff and each defendant.

13. Venue is proper in this Court pursuant to 28 U.S.C. §1391(a) by virtue of the fact that Bayer sold Yaz/Yasmin in the State of Missouri, subjecting defendants to personal jurisdiction in this action and making it a "resident" of this judicial district.

FACTUAL BACKGROUND

Nature of the Case

14. Plaintiff Alaina Ferrara brings this case against Defendants for damages associated with Plaintiff Alaina Ferrara's ingestion of the pharmaceutical drug Yaz/Yasmin (ethinyl estradiol and drospirenone), an oral contraceptive designed, manufactured, marketed, and distributed by Defendants. Specifically, as a direct result of her use of Yaz/Yasmin, Plaintiff Alaina Ferrara suffered from Gallbladder disease.

Bayer's Combined Oral Contraceptives - Yaz and Yasmin

15. Yaz and Yasmin are birth control pills manufactured and marketed by Defendants. They are combination oral contraceptives, or "COCs," meaning that they contain an estrogen component and a progestin component. Together, these steroidal components work together in COCs to suppress ovulation, fertilization, implantation and thus prevent pregnancy.

16. Yaz and Yasmin were approved by the Food and Drug Administration for marketing in 2006 and 2001, respectively.

Yaz and Yasmin Contain a "Fourth Generation" Progestin

17. The estrogen component in Yaz/Yasmin is known generically as ethinyl estradiol. The progestin component is known as drospirenone. Yasmin contains 39 mcg of ethinyl estradiol, and Yaz contains 20 mcg of ethinyl estradiol. Both products contain 3 milligrams of drospirenone.

18. Yaz and Yasmin are different from other combined hormonal birth control pills in that they contain drospirenone, a progestin that is unlike other progestins available in the United States and was never before marketed in the United States prior to its use in Yaz/Yasmin.

19. Yaz and Yasmin contain the same estrogen component, ethinyl estradiol which has been used in the lower dose birth control pills for decades.

20. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yaz/Yasmin marketed under the trade name Ocella.

21. Since drospirenone is new, there is insufficient data available to support its safe use, particularly compared with second generation progestins. In fact, studies performed

prior to FDA approval indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.

22. During the brief time that Yaz/Yasmin have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.

23. In fact, in less than a five-year period, from the first quarter of 2004 through the third quarter of 2008, over 50 reports of death among users of Yaz/Yasmin have been filed with the FDA.

24. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, heart attack, stroke, and gallbladder diseases in women in their child bearing years.

25. Some deaths reported occurred in women as young as 17 years old.

26. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yaz/Yasmin.

Over-Promotion of Yasmin and Yaz

27. Defendants market Yaz/Yasmin as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.

28. However, because Yaz/Yasmin contain the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.

29. For example, prior to its sale to Defendant Bayer in 2006, Defendant Berlex Laboratories promoted Yasmin's fourth generation progestin, drospirenone, by stating, "Ask about Yasmin, and the difference a little chemistry can make."

30. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone was a benefit compared to the progestin used in other combined oral contraceptives, and issued a warning letter stating, "FDA is not aware of substantial evidence of substantial clinical experience demonstrating that Yasmin is superior to other COCs or that the drospirenone in Yasmin is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone [.]”

31. The FDA's warning letter continued by stating that the advertisement failed "to communicate that the potential to increase potassium is a risk" or that "increased serum potassium can be dangerous."

32. More recently, Defendants advertised that its product Yaz/Yasmin was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the less serious condition of premenstrual dysphoric disorder or "PMDD."

33. Defendants also advertised that Yaz/Yasmin contained the added benefit of preventing or reducing acne.

34. In response, on October 3, 2008, the FDA issued another warning letter to Defendant Bayer for the misleading advertisement, reiterating that the marketing was misleading because it promoted Yaz/Yasmin for medical conditions beyond the limits of the FDA approval, and adding that "Yaz/Yasmin has additional risks because it contains the progestin, drospirenone ... which can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems."

35. The FDA further warned in its October 3, 2008 letter that Yaz/Yasmin "does not result in completely clear skin" and that Defendants' "TV Ads misleadingly overstate the efficacy of the drug."

36. Indeed, the FDA felt Defendants' over-promotion was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz/Yasmin advertisements regarding acne and premenstrual syndrome.

37. Bayer ultimately agreed to spend at least \$20 million on corrective TV advertisements and to submit all Yaz/Yasmin advertisements to the FDA for advanced screening for the next six years.

Plaintiff's Use of Yaz/Yasmin and Resulting Injuries

38. As a result of Defendants' claims regarding the effectiveness and safety of Yaz/Yasmin, Plaintiff Alaina Ferrara's medical provider prescribed and Plaintiff Alaina Ferrara began using Yaz/Yasmin in or about February, 2009.

39. As a direct and proximate result of using Yaz/Yasmin, Plaintiff Alaina Ferrara suffered from Gallbladder Disease and resulting injuries described herein.

40. Prior to Plaintiff Alaina Ferrara's use of Yaz/Yasmin, Defendants knew or should have known that use of Yaz/Yasmin created a higher risk of Gallbladder Disease than other oral contraceptives on the market, including but not limited to second generation oral contraceptives, and that, when taken as directed, such use was unreasonably dangerous to consumers.

41. Therefore, at the time Plaintiff Alaina Ferrara used Yaz/Yasmin, Defendants knew or should have known that the use of Yaz/Yasmin created an increased risk to consumers of serious personal injury, including, but not limited to, Gallbladder Disease, Pulmonary Embolism (PE) and a Deep Vein Thrombosis (DVT), heart attacks, stroke, and even death.

42. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yaz/Yasmin, Defendants failed to warn Plaintiff Alaina Ferrara and/or her health care providers of said serious risks before she used the product.

43. Had Plaintiff Alaina Ferrara and/or her health care providers known the risks and dangers associated with Yaz/Yasmin, she would not have used Yaz/Yasmin and would not have suffered from Gallbladder Disease.

44. As a direct and proximate result of her use of Yaz/Yasmin, Plaintiff Alaina Ferrara suffered physical injury, including but not limited to, conscious pain and suffering, as a result of Gallbladder Disease.

45. As a direct and proximate result of Plaintiff Alaina Ferrara's use of Yaz/Yasmin, Plaintiff Alaina Ferrara has suffered and will continue to suffer pecuniary losses.

FIRST CAUSE OF ACTION

Strict Products Liability Defective Manufacturing

46. Plaintiff Alaina Ferrara incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

47. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yaz/Yasmin.

48. The Yaz/Yasmin birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants were expected to and did reach the consumer without any alterations or changes.

49. The Yaz/Yasmin birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, were defective in their manufacture and construction when they left the hands of Defendants in that they deviated from

product specification such that they were unreasonably dangerous to an ordinary user or consumer and posed a serious risk of injury and death.

50. As a direct and proximate result of Plaintiff Alaina Ferrara's use of Yaz/Yasmin as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff Alaina Ferrara suffered personal injuries, and Plaintiff suffered economic and non-economic damages.

51. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiff Alaina Ferrara's rights, so as to warrant the imposition of punitive damages.

SECOND CAUSE OF ACTION

Strict Products Liability Design Defect

52. Plaintiff Alaina Ferrara incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

53. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yaz/Yasmin.

54. The Yaz/Yasmin birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants were expected to and did reach the consumer without any alterations or changes.

55. The Yaz/Yasmin birth control pills manufactured and supplied by Defendants were defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or they were more dangerous than an ordinary consumer would expect.

56. The foreseeable risks associated with the design or formulation of the Yaz/Yasmin birth control pills, include, but are not limited to, the fact that the design or formulation of Yaz/Yasmin is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

57. As a direct and proximate result of Plaintiff Alaina Ferrara's use of Yaz/Yasmin as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff Alaina Ferrara suffered personal injuries, economic and non-economic damages, including pain and suffering.

58. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiff Alaina Ferrara's rights, so as to warrant the imposition of punitive damages.

THIRD CAUSE OF ACTION

Strict Products Liability Defect Due to Inadequate Warning

59. Plaintiff Alaina Ferrara incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

60. The Yaz/Yasmin birth control pills manufactured and supplied by Defendants were defective due to inadequate warning or instruction and was unreasonably dangerous to the ordinary user or consumer because Defendants knew or should have known that the product created significant risks of serious bodily harm and death to consumers and they failed to adequately warn consumers and/or their health care providers of such risks.

61. The Yaz/Yasmin birth control pills manufactured and supplied by Defendants were defective due to inadequate post-marketing warning or instruction and were unreasonably dangerous to the ordinary user or consumer because, after Defendants knew or should have

known of the risk of serious bodily harm and death from the use of Yaz/Yasmin, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and death.

62. As a direct and proximate result of Plaintiff Alaina Ferrara's use of Yaz/Yasmin as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff Alaina Ferrara suffered personal injuries, economic and non-economic damages.

63. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiff Alaina Ferrara's rights, so as to warrant the imposition of punitive damages.

FOURTH CAUSE OF ACTION

Negligence

64. Plaintiff Alaina Ferrara incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

65. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of Yaz/Yasmin into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events.

66. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Yaz/Yasmin into interstate commerce in that Defendants knew or should have known that the product caused such significant bodily harm or death and was not safe for use by consumers.

67. Defendants also failed to exercise ordinary care in the labeling of Yaz/Yasmin and failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury or death due to the use of Yaz/Yasmin.

68. Despite the fact that Defendants knew or should have known that Yaz/Yasmin posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market Yaz/Yasmin for use by consumers.

69. Defendants knew or should have known that consumers, including Plaintiff Alaina Ferrara, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

70. As a direct and proximate result of Defendants' negligence, Plaintiff Alaina Ferrara suffered personal injuries, economic and non-economic damages.

71. Defendants' conduct as described above, including but not limited to its failure to adequately test Yaz/Yasmin, to provide adequate warnings, and its continued manufacture, sale and marketing of the product when it knew or should have known of the serious health risks it created, evidences malicious actions, aggravated or egregious fraud, and/or intentional disregard of the rights of Plaintiff Alaina Ferrara, so as to warrant the imposition of punitive damages.

FIFTH CAUSE OF ACTION

Negligent Misrepresentation and/or Fraud

72. Plaintiff Alaina Ferrara incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

73. Defendants are the manufacturers, designers, distributors, sellers or suppliers of Yaz/Yasmin and made representations to Defendant and her healthcare providers regarding the character or quality of Yaz/Yasmin for guidance in their decision to select Yaz/Yasmin.

74. Specifically, Defendants represented that their product was just as safe or safer, and just as effective or more effective, than other birth control products on the market.

75. Defendants' representations regarding the character or quality of Yaz/Yasmin were untrue.

76. Defendants had actual knowledge based upon studies, published reports and clinical experience that its product Yaz/Yasmin created an unreasonable risk of serious bodily injury and death to consumers, or should have known such information.

77. Defendants negligently and/or intentionally misrepresented or omitted this information in its product labeling, promotions and advertisements and instead labeled, promoted and advertised its product as safer and more effective than other types of oral contraceptives in order to avoid losses and sustain profits in its sales to consumers.

78. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining or communicating information to Plaintiff Alaina Ferrara and her healthcare providers.

79. Plaintiff Alaina Ferrara and her healthcare providers reasonably relied to Plaintiff's detriment upon Defendants' misrepresentations and/or omissions in its labeling, advertisements, and promotions concerning the serious risks posed by the product. Plaintiff Alaina Ferrara reasonably relied upon Defendants' representations to her and/or her healthcare providers that Yaz/Yasmin was safer than other type of oral contraceptives for human

consumption and/or use and that Defendants' labeling, advertisements and promotions fully described all known risks of the product.

80. As a direct and proximate result of Defendants' negligent and/or intentional misrepresentations or omissions, Plaintiff Alaina Ferrara suffered personal injuries and economic and non-economic damages, including pain and suffering.

81. Defendants' actions and omissions as identified in this Complaint demonstrate malicious actions, aggravated or egregious fraud, and/or intentional disregard of Plaintiff Alaina Ferrara's rights so as to warrant the imposition of punitive damages.

SIXTH CAUSE OF ACTION

Intentional and Wanton Conduct and Request for Punitive Damages

82. Plaintiff Alaina Ferrara hereby adopts and incorporates by reference all the above allegations.

83. At all material times, the Defendants knew or should have known that Yaz/Yasmin was inherently dangerous.

84. Despite their knowledge, the Defendants continued to aggressively market Yaz/Yasmin to consumers, including Plaintiff Alaina Ferrara, without disclosing its dangerous side effects when safer alternative products existed.

85. Despite Defendants' knowledge of Yaz/Yasmin's defective and unreasonably dangerous nature, Defendants continued to test, design, develop, manufacture, label, package, promote, market, sell and distribute, it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff Alaina Ferrara, in conscious disregard of the foreseeable harm caused by Yaz/Yasmin.

86. The Defendants' conduct was intentional and/or wanton.

87. The Defendants' conduct as described above, including, but not limited to, their failure to adequately test their product, to provide adequate warnings, and their continued manufacture, sale, and marketing of their products when they knew or should have known of the serious health risks created, evidences a flagrant disregard of human life as to warrant the imposition of punitive damages as the acts or omissions were committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including Plaintiff Alaina Ferrara.

SEVENTH CAUSE OF ACTION

Breach of Express Warranty as to Bayer Defendants

88. Plaintiff Alaina Ferrara incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

89. The Bayer Defendants expressly warranted that Yaz/Yasmin was a safe and effective prescription contraceptive.

90. The Yaz/Yasmin birth control pill manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to consumers when taken in recommended dosages.

91. As a direct and proximate result of the Bayer Defendants' breach of warranty, Plaintiff Alaina Ferrara has suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

EIGHTH CAUSE OF ACTION

Breach of Implied Warranty as to Bayer Defendants

92. Plaintiff Alaina Ferrara incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

93. At the time the Defendants designed, manufactured, marketed, sold, and distributed Yaz/Yasmin for use by Plaintiff Alaina Ferrara, Defendants knew of the use for which Yaz/Yasmin was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

94. Plaintiff Alaina Ferrara reasonably relied upon the skill and judgment of the Defendants as to whether Yaz/Yasmin was of merchantable quality and safe for its intended use and upon the Defendants' implied warranty as to such matters.

95. Contrary to such implied warranty, Yaz/Yasmin was not of merchantable quality or safe for its intended use, because the product was reasonably dangerous as described above.

96. As a direct and proximate result of the Defendants' breach of warranty, Plaintiff Alaina Ferrara has suffered harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff Alaina Ferrara prays for relief as follows:

1. Compensatory and punitive damages in excess of the jurisdictional amount;
2. Medical expenses and other economic damages in an amount to be determined at trial of this action;
3. Attorneys' fees, expenses, and costs of this action;
4. Punitive damages in excess of the actual damages award;
5. Pain and suffering; and
6. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff Alaina Ferrara hereby demands a trial by jury on all issues so triable.

Dated: March 23, 2010

/s/ Brian Timothy Meyers

Brian Timothy Meyers MO # 32636

Peter K. Andreone MO # 60631

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